

## PRODUCT DISRUPTION BRIEF

## Fetal spiral electrodes (updated August 20)

All Cardinal supply challenge have recovered and products are available to order.

## Current conditions

In November 2022, Philips became aware of a *potential* safety issue with the Fetal Spiral Electrode based on an increasing number of customer complaints related to the spiral tip of the FSE breaking off during use. As a result, the FDA issued a **Class II Correction (Recall)** of the Fetal Spiral Electrode.

- Philips has exited the market for Fetal Spiral Electrodes; however, they still make the monitors.
- DECG Legplate Adapter Cable and Attachment Electrode were discontinued 12/31/2022

Due to the limited number of alternative products available, Cardinal has proactively increased their forecast expectations to allow them to better support the full anticipated market need. All Cardinal supply challenge have recovered and products are available to order.

## Recall mitigation strategy

For the Philip's recall, providers should complete the Urgent Field Safety Notice Response Form online to submit both their acknowledgement of this recall (mandatory) and actions taken, as well as request for credit (optional). To request credit, go to URL: <https://forms.office.com/r/GsLVh2gYZi>.

If you choose, discard all FSEs sold by Philips and source from an alternative supplier available in your country. If you choose to discard the FSEs, we will issue a credit after you complete the online response form.

## Alternatives

**Cardinal Health** offers a Philips-compatible cable that can be ordered directly through them. Cardinal offers the following alternatives for the Kendall Fetal Spiral Electrode:

Product #	Description	Alternative	Alternative description
31479549	Kendall FSE 2100	Philips 989803137631	Fetal spiral electrode, single spiral
		Vyaire 7000AAO	Fetal spiral electrode

**Cardinal** has also provided the following matrix showing component compatibility to patient monitoring equipment:

FSE Cable	Description	Compatible OEM Fetal Monitors	Required OEM Patent Modules
31479754	FCB 100 cable, HP 8040A	Philips/HP 8040A	N/A
31479846	FCB 300 cable, Philips, 2'	Philips 50 IX (M1350A), Series 50XM (M1350B), Series 50XMO (M1350C), and Series 50 IP-2 (M1353A)	DECG Transducer (M1357A) or Patient Modules (M1364A, M1365A)
		Philips Avalon FM30 (M2703A) and FM50 (M2705A)	Avalon Toco + Transducer (M2735A) or Patient Module (M2738A)
		Philips Avalon CTS (M2720A)	Wireless ECG Transducer (M2727A)
50000331	FCB 308 cable, Philips, 8'	Philips 50 IX (M1350A), Series 50XM (M1350B), Series 50XMO (M1350C), and Series 50 IP-2 (M1353A)	DECG Transducer (M1357A) or Patient Modules (M1364A, M1365A)
		Philips Avalon FM30 (M2703A) and FM50 (M2705A)	Avalon Toco + Transducer (M2735A) or Patient Module (M2738A)
		Philips Avalon CTS (M2720A)	Wireless ECG Transducer (M2727A)
31479812	FCB 400 cable, GE Corometrics round	GE Corometrics 170 series (models 173 & 174)	N/A
50000107		GE Corometrics 120 series (models 126, 128 & 129)	N/A



To learn more, please contact:  
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As the nation's largest member-driven health care performance improvement company, Vizient provides solutions and services that empower health care providers to deliver high-value care by aligning cost, quality and market performance. With analytics, advisory services and a robust sourcing portfolio, we help members improve patient outcomes and lower costs.

FSE Cable	Description	Compatible OEM Fetal Monitors	Required OEM Patent Modules
	FCB 700 cable, GE Corometrics rectangular	GE Corometrics 250cx series (models 256cx & 259cx)	N/A

**GE** has two Fetal Scalp Electrodes (FSEs) for use with the Corometrics™ series monitors.

2109004-001	31479812, Fetal Spiral Electrode Cable, Round connector
2109006-001	50000095, Fetal Spiral Electrode, Attachment Pad, Large, Single Patient Use, 50/Box
2109005-001	50000107, Fetal Spiral Electrode Cable, Rectangular connector
2109002-001	31479549, Fetal Spiral Electrode, Single Helix, Single Patient Use, 50/Box

*Note: Electrode 2109002-001 can only be used with cable 2109004-001 (Round Connector) and leg plate 2109006-001 or with cable 2109005-001 (Rectangular Connector) and leg plate 2109006-001*

To further support FSE needs, **Vyaire Medical** Qwik Connect FSE has been tested and validated for use with the GE Healthcare Corometrics series monitors.

7000AAO	Qwik Connect Plus Fetal Spiral Electrodes, 50/Box
2464AAO-20	Qwik Connect Plus Spiral Leg Plate Disposable Attachment Pads, 50/Box
1591AAO	Fetal Spiral Electrode Cable, Rectangular connector
1590AAO	Fetal Spiral Electrode Cable, Round connector

*Note: Electrode 7000AAO can only be used with Cable 1590AAO (Round Connector) and leg plate 2464AAO or with cable Cable 1591AAO (Rectangular Connector), and leg plate 2464AAO.*

## Additional resources

Supply assurance webpage; Vizient Newsroom



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Questions? Contact [disasterresponse@vizientinc.com](mailto:disasterresponse@vizientinc.com), [pharmacyquestions@vizientinc.com](mailto:pharmacyquestions@vizientinc.com), [novaplus@vizientinc.com](mailto:novaplus@vizientinc.com)